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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,468	07/30/2003	Nils Holmstrom	P03,0233	9181

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SCHIFF HARDIN, LLP
PATENT DEPARTMENT
6600 SEARS TOWER
CHICAGO, IL 60606-6473

EXAMINER

MORALES, JON ERIC C

ART UNIT	PAPER NUMBER
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3766

MAIL DATE	DELIVERY MODE
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06/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/630,468

Applicant(s)

HOLMSTROM, NILS

Examiner

Jon-Eric C. Morales

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/22/2007 and 12/15/2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 4-9 13-14, 16-21, 25-27, 28-29, and 31-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Obel et al. (US Patent No 5199428). Regarding claims 1, 4, 13, 16, 25, 28, and 31, Obel discloses a cardiac stimulating system that contains a control circuit (fig. 2). The device also has electrode sensors for detecting blood oxygen saturation and the pH level. These electrode sensors are located on a lead and placed in the coronary sinus (column 3 lines 42-47). The device also has another sensor with conjunction to the coronary sinus sensor to measure the electrocardiogram ECG of the heart, which is coupled to the circuitry (column 7 lines 8-15).

Regarding claims 2, 5, 14, 17, 29, and 32 the pH and blood oxygen saturation values recorded when the ventricles are filled with blood (diastole, first value) as well as during contraction of the heart (systole, second value) (column 2 lines 11-15, column 5 lines 9-11, 30-39, column 7 lines 8-15, column 9 lines 25-35).

Regarding claims 6, 18, and 33, Obel discloses the oxygen and pH sensors trigger the detection of ischemia. The system is configured to store the values of the oxygen and pH sensor values that satisfy the programmed thresholds (column 6 lines

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45-53). Once the condition of ischemia is detected stimulation occurs providing pacing therapies (column 6 lines 66-68 column 7 lines 1-4).

With respect to claims 7, 8, 19, 20, 34, and, 35, Obel discloses a predetermine condition includes having the pH value fall below the rate of change of the pH threshold (lower first value) as well as the blood oxygen falling above a rate of change of blood oxygen threshold (higher second value) (column 7 lines 26-45).

Concerning claims 9, 21, 26 and 36, Obel discloses the delivery of atrial and ventricular stimulation pulses in the heart by the control circuit (column 8 lines 55-56). The control of the pulses is determined by the thresholds values that the pH and oxygen sensors obtain (column 25-39).

Regarding claim 27, Obel discloses a lead that is placed in the right ventricle of the patient's heart (column 5 lines 37-39, column 9 lines 28-30).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3, 15, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US Patent No 5199428). Obel discloses the claimed invention except for detecting the second value in said second portion with a final 70% of said diastolic portion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to detect the second value in said second portion with a final 70%

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of said diastolic portion, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

5. Claims 11, 12, 23, 24, 38, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US Patent No 5199428) as applied to claims 1, 13 and 28 above, and further in view of Jensen et al. (US Patent No. 6752765). Obel discloses the invention substantially as claimed however does not show the implantable monitoring device having a warning signal generator and a physical activity level sensor. Jensen discloses the use of an activity sensor such as an accelerometer or a piezoelectric transducer that can be used to verify if the patient is at rest or not (column 5 lines 8-15). This will help to regulate the pacing therapies being delivered to the patient. Also Jensen discloses the system having an alarm or indicator (warning signal) that is triggered so the clinician may be alerted when the patient's condition changes. Therefore it would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify the device of Obel by adding a activity sensor and a alarm signal as taught by Jensen in order to facilitate the regulation of pacing therapies being delivered to a patient and to be able to signal the clinician when the patient's condition changes.

6. Claims 10, 22 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US Patent No 5199428) as applied to claims 1, 13 and 28, and further in view of Hill et al. (US 2002/0107553). Obel discloses the invention substantially as claimed however does not show the therapeutic device having a drug delivery to a person whom heart-monitoring devices implanted. Hill discloses a drug delivery system included within the implanted device that may be used together with the electrical stimulation. This drug delivery system provides biologically active agent to the tissues of patients to prevent anticipated or detected physiological insults. Therefore it would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify the device of Obel by adding drug delivery system as taught by Hill in order to [prevent anticipated or detected physiological insults to the patient.

Conclusion

The following patent and patent application publications are cited and further show the state of the art with respect to *(invention)* in general:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon-Eric C. Morales whose telephone number is 571-272-3107. The examiner can normally be reached on Monday through Friday from 8am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jon-Eric Morales/
Patent Examiner
Art Unit 3766

JEM

Carl Layno
Acting Supervisory Patent
Examiner
Art Unit 3766


CARL LAYNO
PRIMARY EXAMINER